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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/626,076	07/24/2003	Andrea Venturelli	71067	4532

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WASHINGTON, DC 20004

EXAMINER

MEHTA, BHISMA

ART UNIT

PAPER NUMBER

3767

NOTIFICATION DATE

DELIVERY MODE

07/22/2008

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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### Office Action Summary

**Application No.**

10/626,076

**Applicant(s)**

VENTURELLI, ANDREA

**Examiner**

BHISMA MEHTA

**Art Unit**

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**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 28 April 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,2,4-15 and 17-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-15 and 17-22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/S5108)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_
- Paper No(s)/Mail Date \_\_\_\_\_

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 28 2008 has been entered.

### ***Specification***

2. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: The specification fails to disclose a portion of the guide tube adjacent to the guide tube proximal end resting on the outside of the deflected and inclined part of the main tube.

### ***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1, 2, 4-15, and 17-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Keith (U.S. Patent No. 5,156,594) in view of Dirks et al (U.S. Patent No. 5,846,246). In Figure 2, Keith shows a catheter structure or side port assembly having a main tube (22), a distal tube (82), a guide tube (80), and a balloon (38). In Figure 7, Keith shows the section of the catheter structure or side port assembly having a main tube (22C), a distal tube (82C), and a guide tube (80C). The main tube (22C) is formed from multiple tube sections (64C, 66C). The main tube has a lateral opening (68, 119). A portion of the guide tube (80C) extends into the distal tube (82C) and a portion of the guide tube (80C) adjacent to the proximal end (100C) of the distal tube is located adjacent to the distal end (shown at 66C) of the main tube. The guide tube (80C) has an opening at the proximal end (92C) of the guide tube on one side of the main tube (22C). A portion of the distal tube (82C) adjacent to the proximal end (100C) of the distal tube encloses both a portion of the main tube adjacent to the distal end of the main tube and a portion of the guide tube adjacent to the guide tube proximal end. A portion of the guide tube adjacent to the proximal end of the guide tube extends into the lateral opening (119) of the main tube and into the distal tube. Keith also shows an inflation lumen (62C, 125, 104C) and a lumen (52C) for a guide thread. In Figure 2, a portion of the proximal end (100) of the distal tube (82) is flared. Keith teaches joining or sealing the ends of the different parts of the catheter structure by suitable means such as by a solder joint which is a form of heat sealing. The proximal ends of the guide tube and the distal tube are beveled at the lateral opening as seen in the figures. The multiple sections of the main tube have different material compositions, different

thicknesses, and different rigidities and Keith teaches that the guide tube and the distal tube are formed from materials different that that of the main tube. In line 31-33 of column 7, Keith teaches that the guide tube and the distal tube may be formed of the same material or from materials different from one another. Keith discloses the method for manufacturing the catheter structure as claimed. Keith discloses the catheter structure substantially as claimed. Even though Keith shows a part of the distal end (72) of the main tube (22) which is deflected and inclined towards an inside of the main tube, Keith is silent on a portion of the guide tube adjacent to the proximal end of the guide tube resting on the outside of the deflected and inclined part of the main tube. It should be noted that Keith shows the edge of the lateral opening (119) of the main tube (22) in Figure 7 which can also be considered to be deflected and inclined towards an inside of the main tube. Dirks et al disclose a balloon catheter structure in the same field of endeavor. In Figure 4, Dirks et al show a proximal end of a guide tube (96) located in a lateral opening (106) of a main tube (102) where a part of the main tube is deflected and inclined toward an inside of the main tube and where a portion of the guide tube adjacent the proximal end of the guide tube rests on the outside of the deflected and inclined part of the main tube. It would have been obvious to one having ordinary skill in the art at the time the invention was made to extend the guide tube of Keith such that the proximal end of the guide tube rests on the outside of the deflected and inclined part of the main tube as taught by Dirks et al as Dirks et al teach that it is well known to provide a portion of the guide tube that extends out of the lateral opening

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and rests on a part of the main tube so that instruments such as a guide wire can be more easily manipulated and inserted into the guide tube during a surgical procedure.

5. Claims 21 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Keith in view of Dirks et al as applied to claim 20 above, and further in view of Zarbatany et al (U.S. Patent No. 6,030,405). Keith and Dirks et al disclose the method for manufacturing the catheter structure substantially as claimed. However, Keith and Dirks et al are silent on the insertion of expanders into the distal end of the main tube and the proximal end of the guide tube during the heat-sealing operation. Zarbatany et al teach inserting expanders into the ends of tubes that will become a lumen for a guide thread or an inflation lumen and removing the expanders after use in the same field of endeavor of using heat-sealing to join the different sections of a catheter structure. It would have been obvious to one having ordinary skill in the art at the time the invention was made to form the lumens of Keith by using expanders as taught by Zarbatany et al as Zarbatany et al teach that it is well known to use expanders to form lumens when using heat-sealing to form a catheter structure.

### ***Double Patenting***

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir.

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1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 1, 2, 4-15, and 18 are rejected on the ground of nonstatutory

obviousness-type double patenting as being unpatentable over claims 1-15 of U.S.

Patent No. 6,635,029. Although the conflicting claims are not identical, they are not

patentably distinct from each other because the claims are all drawn to a rapid

exchange catheter.

### ***Response to Arguments***

8. Applicant's arguments with respect to claims 1, 2, 4-15, and 17-22 have been considered but are moot in view of the new ground(s) of rejection. It should be noted that the amendments to the claims resulted in the nonstatutory obviousness-type double patenting rejection of claims 1, 2, 4-15, and 18.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BHISMA MEHTA whose telephone number is (571)272-3383. The examiner can normally be reached on Monday through Friday, 7:30 am to 3:00 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Simons can be reached on 571-272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bhisma Mehta/

Examiner, Art Unit 3767

/Kevin C. Simons/

Supervisory Patent Examiner, Art Unit 3767